

REMARKS

Following entry of the foregoing amendments, claims 1-11, 13-16, 18-20, and 23-37 constitute the pending claims in the present application. Claims 1-11 and 13 are withdrawn. Claims 14-16, 18-19, and 22-28 stand rejected. Claims 6, 10-11, 14-16, and 23-31 are amended to correct matters of form. Claims 32-37 are newly added.

Claim 14 is also amended to incorporate matter from claim 22 in order to more particularly claim the present invention. Accordingly, claim 22 is now cancelled. This amendment presents no new matter.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action of May 18, 2005.

1. Withdrawal of Rejections - 35 U.S.C. 112, first paragraph

Applicants note with appreciation the withdrawal of rejections under 35 USC 112, first paragraph, of claims 14-16 and 22-29 for lack of enablement and of claim 20 for lack of written description.

2. Withdrawal of Rejections - 35 U.S.C. 103 (a) over Agrawal

Applicants note with appreciation the withdrawal of rejections of claims 14-16, 18-20, and 22-31 under 35 USC 103(a) over U.S. 5,691,316 to Agrawal et al. ("Agrawal").

3. Rejection based on 35 U.S.C. 103 (a) over Santus

Claims 14-16, 18-19, and 22-28 are rejected as being unpatentable over WO 99/47172 to Santus et al. ("Santus"). Since claim 22 is cancelled, the rejection is rendered moot for this claim. Applicants respectfully traverse the rejection of the remaining claims.

Pursuant to MPEP 2142:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, and not based on applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Office correctly submits that Santus "teaches pharmaceutical compositions of oral administration comprising cyclodextrines and therapeutic agents." However, the Office incorrectly states that Santus "substantially teaches the compositions set forth in the [present] claims" and that the pending claims are therefore *prima facie* obvious. Applicants contend that Santus does not teach all the limitations of the present claims and, therefore, does not teach the present compositions. In particular, at no point does Santus teach or suggest *cyclodextrin-containing polymers* as recited in the pending claims. Each reference to cyclodextrins in Santus refers to *individual* cyclodextrins. In the eight examples disclosed in Santus, all employ *individual* cyclodextrins. Indeed, Santus does not substantially teach the compositions set forth in the present claims, since, as previously argued by Applicants in overcoming the prior obviousness rejection over Agrawal, a cyclodextrin-containing polymer is not obvious in light of an *individual* cyclodextrin, and the Office Action lacks any evidence or reasoning to the contrary. Thus, Santus does not teach all the elements of the instant invention. One of skill in the art would have realized that large differences in chemical and physical properties can exist between polymers and their corresponding individual monomers. Since it is well established that a compound and its properties are inseparable (See *In re Papesch*, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963)), modification of an individual compound into a polymer is unobvious because each can have different properties from the other. Given these considerations, one of skill in the art would have no motivation or expectation of success in modifying the individual cyclodextrins of Santus to provide a cyclodextrin-containing polymer.

Furthermore, Santus does not teach or suggest "a method of preparing a composition, comprising combining a therapeutic agent, a cyclodextrin-containing polymer having host and/or guest functionality, and a complexing agent *comprising at least one functional group and at least one host/guest moiety that forms an inclusion complex with a host/guest moiety of said cyclodextrin containing polymer...*" as recited by the instant claims as currently amended. In fact, Santus does not teach or suggest any sort of inclusion complex between any polymer and any complexing agent recited therein. As such, Santus again does not teach or suggest all the limitations of the present claims, and one of ordinary skill in the art would have had no

motivation or reasonable expectation of success in drastically modifying the Santus method to arrive at the present invention. As such the disclosure of Santus and cannot render the present claims *prima facie* obvious.

The Office Action states that “absent objective evidence to the contrary, the physical characteristics of the compositions are within the motivation of those of ordinary skill, and therefore, *prima facie* obvious.” Applicants disagree and submit that this position by the Examiner is contrary to established patent examining procedure. Notably, MPEP 2143.01 states that “the level of skill in the art cannot be relied upon to provide the suggestion to combine references (*Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999)).” Hence, Applicants assert that, pursuant to MPEP 2143.01, if an obviousness rejection of the pending claims over Santus is to be maintained that the Office must provide evidence and rationale supporting suggestion or motivation for one of ordinary skill in the art to have modified the Santus teachings at the time of filing of the present application. The “teaching, suggestion or motivation [to combine teachings must be] found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art” (MPEP 2143.01). In the outstanding Action, the Office has provided no such reasoning to support an argument that one of ordinary skill in the art, at the time of filing, would have modified the Santus teachings to arrive at the present invention. Absent such evidence on motivation, a *prima facie* case for obviousness over the Santus disclosure cannot be maintained.

In conclusion, Applicants assert that *none* of the three criteria for establishing a *prima facie* case of obviousness have been presented. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection over Santus.

Allowable/Objected Claims

Applicants note with appreciation that claims 20 and 29-31 have been found allowable outside of their dependence on a rejected claim. The present amendments to these claims are strictly for matters of form, such as correcting for proper antecedence, and should in no way affect the Office’s finding of allowability.

New Claims

Claims 32-37 are newly added. Support for claim 32 can be found in the specification on page 10, lines 11-14 and page 12, lines 5-7 and 9-10. Support for claim 33 can be found in the specification on page 10, lines 11-12 and page 12, lines 7-8 and lines 10-13. Support for claim 34 can be found in the specification on page 40 line 20. Support for claim 35 can be found in the specification from page 20, line 20 to page 41, line 2 and on page 41, lines 22-24. Support for claim 36 can be found in the specification on page 40, lines 1-22. Support for claim 37, can be found in the specification on page 41, lines 11-24. Accordingly, Applicants assert that claims 32-37 present no new matter.

Co-pending Application

Applicants respectfully bring to the Examiner's attention rejections made in related co-pending U.S. application 10/021,294.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: June 22, 2005

Customer No: 28120
Docketing Specialist
Ropes & Gray LLP
One International Place
Boston, MA 02110
Phone: 617-951-7000
Fax: 617-951-7050

Respectfully Submitted,



David P. Halstead
Reg. No. 44,735